

### **REMARKS**

Claims 1-4, 6, 10, 11, 13, 14, 17, 19-21, and 23 are currently pending in the application. Claims 1, 6, and 21 are the only claims in independent form.

Specifically referring to the Office Action, claims 1-4, 6-8, 10, 11, 17-22, 25, and 26 have been rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. According to the Office Action, the variants claimed do not meet the guidelines on written description. Thus, the specification fails to teach the claimed variants and do not satisfy the written description guidelines because the variants as claimed are broader than SEQ ID NO. 1. In response thereto, the presently pending claims have been amended to be specifically directed towards SEQ ID NO. 1. As a result of the amendments to the claims, reconsideration of the rejection is respectfully requested.

Claims 1-4, 6-8, 10, 11, and 17-26 have also been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Office Action, the specification is enabled for an isolated polypeptide or recombinant immunogenic polypeptide comprising the amino acid sequence of SEQ ID NO. 1 of a *L. intracellularis* hemolysin polypeptide or an immunogenic composition comprising the amino acid sequence of SEQ ID NO. 1 of a *L. intracellularis*

hemolysin polypeptide and one or more carriers diluents, or adjuvants suitable for veterinary or pharmaceutical use. However, the Office Action holds that the specification does not provide reasonable enablement for the variants as set forth in the claims. In response thereto and as set forth above, the presently pending claims have been amended to be specifically towards SEQ ID NO. 1. As a result of the amendments to the claims, reconsideration of the rejection of the claims is respectfully requested.

Claims 13, 14, 23, and 24 have also been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. According to the Office Action, the Office Action holds that one skilled in the art cannot be assured of the availability to practice the invention as claimed in the absence of the availability of the claimed pALK12 plasmid. The Office Action holds that the nucleic acid encoding the hemolysin of the pALK12 plasmid is required to practice the claimed invention. The Office Action holds that evidence of public availability of the expression plasmid of the claimed invention is required. In response thereto, Applicants assure that the deposit has been made under the provisions of the Budapest Treaty and enclose herewith a copy of the Deposit Receipt for the claimed plasmid. Additionally, enclosed herewith is an affidavit stating that the deposit has been accepted by the International Deposit Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on

the present application. As a result, reconsideration of the rejection is respectfully requested.

Claims 1-4, 6-8, 10, 11, 17-22, 25, and 26 have been rejected under 35 U.S.C. § 102(b) as being anticipated by the McOrsit, et al. reference. According to the Office Action, the McOrsit, et al. reference discloses an isolated polypeptide relating to *Lawsonia intracellularis* organisms. More specifically, the Office Action holds that the polypeptides disclosed in the McOrsit, et al. reference are the same as the claimed variants set forth in the presently pending claims of the present application. However, the Office Action holds that SEQ ID NO. 1 is free of prior art.

As is well established, “[a]nticipation under 35 U.S.C. [§] 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.” *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000), *citing*, *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994)(emphasis added). Further, anticipation of the claims can be found only if a reference shows exactly what is claimed; where there are differences between the disclosures of the references and the claim, a rejection must be based on obviousness under Section 103. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985). Additionally, “[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention

must be identically shown in a single reference.” *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)(emphasis added).

As set forth above, the presently pending claims have been amended to be specifically directed towards SEQ ID NO. 1. As a result of the amendments to the claims, the presently claimed invention is not anticipated by the McOrsit, et al. reference. The McOrsit, et al. reference does not disclose the specifically claimed sequence of SEQ ID NO. 1 as set forth in the presently pending claims. As a result, reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

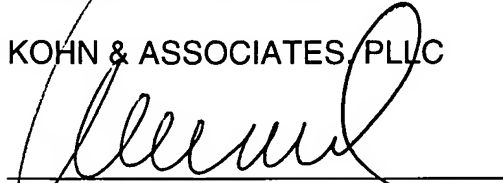
In summary, the presently claimed invention is in condition for allowance, which allowance is respectfully requested. If any remaining issues exist, Applicants respectfully request to be contacted by telephone at 248.539.5050.

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Respectfully submitted,

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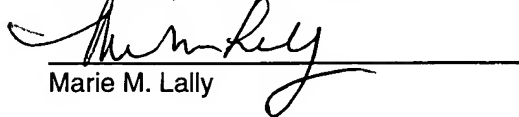
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